

Remarks

Claims 92-119 have been added, claims 35, 59-82, 85, 87, and 91 have been canceled without prejudice, and claims 83-84, 86, and 88-90 have been amended without prejudice. It is noted that claims 73-77 have been canceled as directed to a non-elected invention. Regardless, Applicants reserve the right to prosecute the non-elected invention in a continuing application. As such, claims 83-84, 86, 88-90, and 92-119 are pending after entry of the present amendment. No new matter enters by way of the present amendment. Moreover, such amendments do not require further search or consideration, remove issues for appeal, and are believed to place the claims in condition for allowance. As such, entry of the present amendment is respectfully requested. Support for the foregoing claim amendments may be found throughout the specification, and in the original claims. Specifically, support can be found, for example, at page 4, lines 22-24; page 25, line 29 through page 27, line 12; page 28, lines 22-32; page 29, lines 4-14; page 32, lines 18-20; page 34, lines 6; and Example 1 at page 42, lines 30-35 of the specification as filed.

I. Rejection Under 35 U.S.C. § 112, First Paragraph, Enablement

Claims 35, 59-72, 78, 84, 88, and 90 stand rejected under 35 U.S.C. § 112, first paragraph, for purportedly containing subject matter not described in the specification in such a way as to enable one of skill in the art to make and/or use the invention. The Examiner has indicated that a Deposit Declaration was not included with the Response filed November 18, 2002 (Paper No. 9). Final Action at page 2.

Please find enclosed a Deposit Declaration with an attached copy of the Receipt of an Original Deposit, indicating that hybridoma cell line L106 was deposited at the American Type Culture Collection on November 3, 1993, and given the ATCC designation HB 11483. In light of filing this Deposit Declaration, the rejection under 35 U.S.C. § 112, first paragraph is moot, and withdrawal of this rejection is respectfully requested.

II. Rejection Under 35 U.S.C. § 112, First Paragraph, Written Description

Claims 79-91 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way so to reasonably convey to one skill in the art that the inventors had possession of the claimed invention at the time the application was filed. *See* Final Action at page 7. The Examiner acknowledges that Applicants are in possession of: “a monoclonal antibody and a fragment of said antibody; a humanized antibody and a fragment of said antibody that specifically binds to ACT-4-h-1 of SEQ ID NO: 2.” *Id.* However, to support the rejection, the Examiner argues that Applicants are not in possession of: “a monoclonal antibody and a fragment of said antibody; a humanized antibody and a fragment of said antibody that specifically binds to *any* ACT-4-h-1.” *Id.* Although Applicants traverse the rejection, the rejected claims have been amended without prejudice to facilitate prosecution.

The amended claims recite antibodies or antibody fragments that specifically bind an ACT-4-h-1 receptor. Read in light of the specification, the ACT-4-h-1 receptor is fully described in Figure 5 and as SEQ ID NO: 2. *See* specification at page 18, lines 15-19. According to the Examiner, Applicants have possession of the ACT-4-h-1 receptor of SEQ ID NO: 2. Final Action at page 7. Sequences for ACT-4 receptor variants may be obtained as described in section III of the specification (*see* specification starting on page 21), and antibodies that specifically bind such variants may be included in the scope of the claims. However, the claims are expressly directed to antibodies or antibody fragments that specifically bind an ACT-4-h-1 receptor.

Accordingly, for at least the foregoing reasons, Applicants believe that the pending claims are fully described in the specification as to reasonably convey to one skill in the art that the inventors had possession of the claimed invention at the time the application was filed. As such, the rejection under 35 U.S.C. § 112, first paragraph, written description, is traversed and withdrawal of this rejection is respectfully requested.

III. Rejections Under 35 U.S.C. 112, Second Paragraph

Claims 65, 68 and 71 stand rejected under 35 U.S.C. § 112, second paragraph, for purportedly being indefinite. According to the Examiner, the claims are indefinite for reciting “L106 antibody” without any identifying characteristics. Final Action at page 3.

By the present amendment, any claims referring to the L106 antibody have been amended to recite a monoclonal antibody that specifically binds to an ACT-4-h-1 receptor and is generated by hybridoma HBL106, deposited under ATCC Accession No. HB 11483, thereby providing identifying characteristics of the L106 antibody. Therefore, in light of the present amendment and for at least the reasons provided, it is submitted that this rejection is moot, and withdrawal of the rejection is respectfully requested.

IV. Rejections Under 35 U.S.C. § 102(b)

Claims 59 and 62, 79 stand rejected under 35 U.S.C. §102(b) as being anticipated by Knapp *et al.* (Leucocyte Typing IV, 1989) (hereafter "Knapp"). This rejection is respectfully traversed for at least the reasons which follow.

It is well established that to anticipate a claim, a reference must disclose every element of the claim. *Verdegaal Bros. v. Union Co. of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 U.S.P.Q.2d 1913 (Fed. Cir. 1989). Applicants submit that Knapp does not anticipate the presently pending claims in that significant limitations of the present claims are not disclosed or suggested by the reference.

According to the Examiner, Knapp teaches an L106 antibody. See Final Action at page 3. As previously stated in the Response filed November 18, 2002, Applicants submit that Knapp does not disclose or enable an antibody that specifically binds ACT-4 receptor polypeptides. Although there is mention of an antibody designated L106, the reference is silent with regard to ACT-4. In fact, Knapp classifies L106 antibody as binding CD25. Moreover, the L106 antibody was submitted to the Fourth International Workshop and Conference on Human Leukocyte Differentiation Antigens, Vienna 1989 (*see* specification at page 43, lines 6-9), the results of which are reflected in Knapp, to evaluate the activity of L106 on behalf of the present inventors, and as such constitutes experimental use as suggested by the Examiner in the Office Action mailed July 16, 2002.

Nonetheless, in order to further prosecution, the claims have been amended without prejudice to recite antibodies having characteristics that differ from those of L106 (*e.g.*, at least in terms of amino acid sequence (*see* claims 83-84, 86, and 88-90), binding specificity (*see* claims 92-99), competition for binding (*see* claims 100-108 and 119), agonist activity (*see* claims 109-115), ,

method of production (*see* claims 116-117), or binding affinity (*see* claim 118)). Whatever else Knapp does disclose, the reference does not disclose the presently claimed invention. As such, it is submitted that the present claims are patentable over Knapp, and withdrawal of this rejection is respectfully requested.

V. Rejections Under 35 U.S.C. § 103(a)

Knapp in view of Thorpe et al.

Claims 78 and 80 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Knapp in view of Thorpe *et al.* (Immunological Rev., 1989) (hereafter “Thorpe”). This rejection is respectfully traversed for at least the reasons that follow.

To establish a *prima facie* case of obviousness, the prior art reference (or references when combined) must teach or suggest all of the claim limitations. There must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. The teaching or suggestion to make the claimed combination must be found in the prior art, and not be based on Applicants’ disclosure. *See* M.P.E.P. §§ 2143.01 and 2143.03.

First, the Examiner alleges that the claimed invention differs from Knapp only by the recitation of an immunotoxin comprising L106 antibody fused to a toxin polypeptide. *See* Final Action at page 5. Then, the Examiner states that Thorpe teaches a method of producing immunotoxins to attack tumor cells. *Id.* The Examiner suggests that one of ordinary skill in the art would have been motivated to combine the references to target toxins to tumor cells as taught by Thorpe. *Id.* Applicants respectfully disagree. Neither Knapp nor Thorpe, whether taken together or separately, suggest or motivate one of skill in the art to modify the L106 antibody discussed in Knapp based on the teachings of Thorpe to achieve the presently claimed invention. Even assuming *arguendo* that Knapp is available as prior art, Thorpe does nothing to compensate for the absence of a teaching or suggestion of antibodies that specifically bind an ACT-4-h-1 receptor and have characteristics differing from those of L106.

Applicants respectfully submit that the cited references, alone or in combination, do not render the present claims obvious, since significant limitations of the claims are neither taught nor suggested by the cited references. As such, withdrawal of this rejection is respectfully requested.

Knapp in view of Owens *et al.* and Bird *et al.*

Claims 35, 59-72, 78, 84, 88, and 90 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Knapp in view of Owens *et al.* (J. of Immunol. Method., 1994) (hereafter "Owens") and Bird *et al.* (Science, 1988) (hereafter "Bird"). This rejection is respectfully traversed for at least the reasons which follow.

As stated previously, to establish a *prima facie* case of obviousness, the prior art reference (or references when combined) must teach or suggest all of the claim limitations. There must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. The teaching or suggestion to make the claimed combination must be found in the prior art, and not be based on Applicants' disclosure. See M.P.E.P. §§2143.01 and 2143.03.

Initially, as discussed above, it is submitted that Knapp is not available as prior art. Nonetheless, even assuming *arguendo* that Knapp is prior art, Owens and Bird do nothing to provide a teaching or suggestion of antibodies that specifically bind an ACT-4-h-1 receptor and have characteristics differing from those of L106. As such, Applicants respectfully submit that the cited references do not render the presently pending claims obvious, since significant limitations of the claims are neither taught nor suggested by the cited references. As such, withdrawal of this rejection is respectfully requested.

Conclusion

In view of the foregoing amendments, Applicants believe that the application is in condition for allowance and solicit a Notice of Allowance indicating such at the earliest possible time. The Examiner is encouraged to contact the undersigned should any additional information be necessary.

Respectfully submitted,



David R. Marsh (Reg. No. 41,408)

Milan M. Vinnola (Reg. No. 45,979)

Date: May 30, 2003

ARNOLD & PORTER
555 Twelfth Street, NW
Washington, D.C. 20004
(202) 942-5000 telephone
(202) 942-5999 facsimile